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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,504

11/19/2003

Gordon H. Epstein

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EXAMINER

RYCKMAN, MELISSA K

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/718,504	<b>Applicant(s)</b> EPSTEIN ET AL.	
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19,21-26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19,21-26 and 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/10/09 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 21-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (U.S. Pub. No. 2003/0187474 A1) and further in view of McGuckin, Jr. et al. (U.S. Patent No. 7,331,976).

Keegan teaches an expansible device for use in a tissue tract extending from a skin surface to a blood vessel, the device comprising:

- a tubular member (21) having a lumen, a proximal end, and a distal end
- a first expansible member (26, Fig. 5) disposed on the distal end of the tubular member, the first expansible member having a contracted configuration and an expanded configuration, wherein the first expansible

member consists essentially of a single wire (26) that can be retracted into the lumen of the tubular member (capable of being retracted into lumen) to shift the single wire from a helical expanded configuration to a straightened contracted configuration

- a first deformable membrane at least partially disposed over the first expansible member in the expanded configuration (20, Fig. 5)
- a second expansible member (balloon, Fig. 6) disposed proximal to the first expansible member and on the distal end of the tubular member, the second expansible member having a contracted configuration and an expanded configuration comprising an elongate cylinder having a length sufficient to extend through at least a portion of the tissue tract from the blood vessel to the skin surface (Fig. 6)
- a predetermined volume of air contained within the tubular member inflates the second expansible member so as to provide at least one of radial or axial expansion (inherently a predetermined volume of air will fill the second expansible member)
- the second expansible member has a length in a range from about 0.1 inch to about 2.0 inches (Fig. 5)
- the first and second expansible members are deployed sequentially (Fig. 5-6)

Keegan teaches the claimed invention but does not have the first deformable membrane having a spherical shape when the first expansible member is in the

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expanded configuration, or the second expansible member comprises a coil or spring of wire with a membrane. However, McGuckin teaches:

- wherein the first deformable membrane has a spherical shape when the first expansible member is in the expanded configuration (Fig. 6, element 50)
- the second expansible member (34) comprises a coil or spring of wire (34) with the diameter as defined in the claims (col. 7, ll. 55-67).
- a second deformable membrane (membrane around 34) at least partially disposed over the second expansible member in the expanded configuration (fig. 6)
- ribs on a surface of the second deformable membrane (Fig. 6)
- a reference stop (40) disposed between the first deformable membrane and the distal end of the tubular member (Fig. 6)

It would have been obvious to one of ordinary skill in the art to use the shape of McGuckin with the device of Keegan as the spherical shape may be preferable in different applications, as the front face would be rounded instead of flat, making the entry of the device into a certain body part smoother. The sphere of McGuckin is structurally stonger than the shape of Keegan, because the stress concentration is evenly distributed in a sphere.

Regarding Claims 22 and 24, it would have been obvious to one of ordinary skill in the art to use the second expansible member of McGuckin, as using the struts

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(element 60) of McGuckin in exchange for the balloon of Keegan is well known in the art as using struts performs equally well as a balloon in anchoring the device.

Regarding Claim 23, McGuckin teaches a device for occluding an opening, wherein the second expansible member is of a diameter .19 inches. It would have been an obvious matter of design choice to disclose the diameter of the coil and wire as being within the disclosed range since it appears that the device of Latson performs the task of closing a hole in tissue equally well as that of the disclosed application, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 28, McGuckin teaches a stop between the first deformable member and the distal end of the tubular member, it would have been obvious to one of ordinary skill in the art to use the stop of McGuckin with the device of Keegan as this aides in delivery of the device and expansion and retraction of the device.

Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (U.S. Pub. No. 2003/0187474 A1) and McGuckin, Jr. et al. (U.S. Patent No. 7,331,976), and further in view of Brenneman et al. (US 6071300).

Keegan and McGuckin teach the claimed invention as described in the above rejection, but do not teach the specified locations of the first and second expansible members, however Brenneman teaches the first expansible member is deployed

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against a blood vessel wall (fig. 1) and the second expansible member is deployed against a tissue tract (fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Keegan and McGuckin in the location of Brenneman, as this is common and successful in the art.

The combination of Keegan and McGuckin teach the claimed invention, and further teaches wherein wherein the first and second expansible members are deployed sequentially, but fails to teach wherein the first and second expansible members are deployed simultaneously. It would have been an obvious matter of design choice to modify the method of Keegan by simultaneously deploying the first and second expansible members, since the combination of Keegan and McGuckin is capable of performing that function, and in paragraph 79 of the present application, applicant asserts that it is preferable to deploy the first and second members sequentially, and it appears that the method of the combination of Keegan and McGuckin performs the task of sealing a puncture equally well as that of the present application.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR  
/Melissa Ryckman/  
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773